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EXAMINER

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**BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES**

Paper No. 13

Application Number: 09/139155
Filing Date: 8/24/98
Appellant(s): Flynn et al.

Kimberly Zillig
For Appellant

MAILED
SEP 14 2000
GROUP 2800

EXAMINER'S ANSWER

This is in response to Appellant's brief on appeal filed 7/31/00.

(1) *Real Party in Interest*

A statement identifying the real party in interest is contained in the brief.

(2) *Related Appeals and Interferences*

Art Unit: 2833

A statement identifying the related appeals and interferences which will directly affect or be directly affected by or have a bearing on the decision in the pending appeal is contained in the brief.

(3) *Status of Claims*

The statement of the status of the claims contained in the brief is correct.

(4) *Status of Amendments After Final*

No amendment after final has been filed.

(5) *Summary of Invention*

The summary of invention contained in the brief is correct.

(6) *Issues*

The Appellant's statement of the issues in the brief is substantially correct. The changes are as follows: Regarding claims 2, 4, 5, 11, and 12, the issue is whether the claims are obvious over Stutz Jr., in view of Fain, not just Fain.

(7) *Grouping of Claims*

The Appellant's statement in the brief that certain claims do not stand or fall together is not agreed with because "merely pointing out differences in what the claims cover is not an argument as to why the claims are separately patentable." 37 C.F.R. 1.192(c)(7).

Art Unit: 2833

(8) *Claims Appealed*

After reconsideration, claims 4, 5, 11, and 12 were indicated as being allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. This was communicated to Appellant's attorney on 8/31/00.

(9) *Prior Art of Record*

The following is a listing of the prior art of record relied upon in the rejection of claims under appeal.

5413595	Stutz, Jr.	5-1995
5679026	Fain et al.	10-1997

(10) *Grounds of Rejection*

The following ground(s) of rejection are applicable to the appealed claims:

Claims 1-15 are rejected under 35 U.S.C. 103(a) over Stutz, Jr., ("Stutz") in view of Fain ("Fain"). This rejection is set forth in prior Office action, Paper No. 7., and is repeated here.

Claims 1 through 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stutz, Jr., ("Stutz") in view of Fain et al. U.S. No. 5,679,026 ("Fain").

Stutz teaches a lead 32 comprising an elongated, flexible, electrically insulating main body portion having a proximal and distal end, at least one terminal connector attached to the proximal end of the main body and adapted for coupling the lead to a header assembly of an implantable medical device, at least one electrode embodied within a distal end portion of the

Art Unit: 2833

main body portion, and at least one conductor corresponding with each electrode and electrically insulated by the main body portion, wherein a distal end of each conductor is attached to each corresponding electrode and a proximal end of each conductor is attached to at least one corresponding terminal connector.

Stutz does not teach an adapting member.

Fain teaches an adapter capable of electrical and mechanical coupling to a port of an implantable medical device's header and to a plurality of leads, said adapter comprising:

a terminal connector attached to a proximal end of a main body and adapted for coupling the adapter to a header assembly of an implantable medical device;

a conductor corresponding to an electrode of a connected lead and insulated by the main body of the adapter where the conductor is attached to a corresponding terminal connector.

The adaptor connects to leads and has a plurality of ports adaptable for sealably receiving a terminal connector of a plurality of leads, wherein each port has a conductive terminal block positioned within each port and wherein a jumper wire embedded within the adapter interconnects the terminal block with one of the conductors insulated by the main body of the lead. (Col. 8, lines 25-30: "In this embodiment, two . . . leads are brought together by the header adapter 40 from the connector ports 42, 44 to a single in-line . . . connector 50." Col. 8, lines 48-53: "The lead connector block 64 and the lead connector block (not shown) opposite thereto, are both electrically connected to the lead connector 50 . . . in a manner well-known in the art, e.g., by electrical wires" See also Col. 10, lines 30-45).

Art Unit: 2833

Fain discusses and assumes the leads which are pluggable into the adapter and which are well known in the art and which have an elongated insulated main body portion having a proximal end and a distal end, and an electrode at the distal end of the main body and a lead connector at the proximal end.

At the time of the invention, it would have been obvious to a person of ordinary skill in the art to combine the Fain adapter and the Stutz lead into a unitary lead and adapter. The use of a one piece construction instead of the two piece lead and adapter construction would have been a matter of obvious engineering choice. In re Larson, 340 F.2d 965, 968, 144 USPQ 347, 349 (CCPA 1965).

Per claim 2, in the combination of the Fain adapter and a lead, the adapting member is positioned on the lead adjacent to the proximal end of the main body of the lead.

Per claims 3 and 10, the Fain adapter engages the header assembly of the implantable medical device.

Per claims 6 and 13, the adapting member is contoured to conform to the shape of the header assembly.

Per claims 7 and 14, the adaptor is suitable for receiving the terminal end of a uni-polar lead.

Regarding claims 8 and 15 at the time of the invention, it would have been obvious to a person of ordinary skill in the art to use electrical wire having an outer insulating layer and an

Art Unit: 2833

inner conductive wire for the jumper wire, such wire being well known and commonly used in the art.

(11) Response to Argument

In response to Appellant's arguments against the references (regarding Stutz, Appellant's brief, pages 5-6, 8, 9) individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). Stutz is cited for disclosing a lead, not for disclosing an adapter. Fain is cited for disclosing an adapter, not for disclosing a lead.

At Appellant's brief, page 6, line 15, Appellant asserts that Fain "does not describe electrically connecting more than one lead to a single port of the pulse generator." The examiner disagrees. In Fain, each port (42, 44) has a conductive terminal block positioned within each port and wherein a jumper wire embedded within the adapter interconnects the terminal block with one of the conductors insulated by the main body of the lead. (Col. 8, lines 25-30: "In this embodiment, two . . . leads are brought together by the header adapter 40 from the connector ports 42, 44 to a single in-line . . . connector 50." Col. 8, lines 48-53: "The lead connector block 64 and the lead connector block (not shown) opposite thereto, are both electrically connected to the lead connector 50 . . . in a manner well-known in the art, e.g., by electrical wires" See also Col. 10, lines 30-45). In contradiction to Appellant's statement

Art Unit: 2833

at Appellant's Brief, page 6, line 16-18, Appellant admits that in Fain, "two or more leads inserted into the header adapter lead connector ports (42, 44, 46, 48) can be electrically connected to the same lead connector (50)" Appellant's Brief, page 6, line 33 - page 7, line 1, Fain reference numbers added.

Appellant indicates that the office action combines Stutz's retention and seal structure for retaining a lead. The examiner disagrees. Stutz is relied on for teaching a lead, in particular a lead 32 comprising an elongated, flexible, electrically insulating main body portion having a proximal and distal end, at least one terminal connector attached to the proximal end of the main body and adapted for coupling the lead to a header assembly of an implantable medical device, at least one electrode embodied within a distal end portion of the main body portion, and at least one conductor corresponding with each electrode and electrically insulated by the main body portion, wherein a distal end of each conductor is attached to each corresponding electrode and a proximal end of each conductor is attached to at least one corresponding terminal connector.

Appellant argues that improper hindsight reasoning was used in the rejection. In response to Appellant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the Appellant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

Art Unit: 2833

Appellant argues that “a lead adapter integrated into a lead body was neither suggested or taught by Stutz or Fain.” (Appellant’s brief, page 7, lines 21-22). Appellant’s statement is misleading because what Appellant claims is a lead comprising an adapting member. Appellant never claims that the adapting member is unitarily formed with the lead, which is what Appellant argues that Stutz and Fain do not teach. A lead comprising an adapter, which is what Appellant claims, does not require that the lead and adapter be formed as a single unitary piece. See In re Morris, 43 USPQ.2d 1753, 1758 (Ct. App. Fed. Cir. 1997)(the phrase “integrally formed” covers more than unitary construction). Therefore, regardless of whether a lead adapter unitarily formed with a lead would have been obvious in view of Stutz and Fain, the claimed lead comprising an adapter would have been obvious. Furthermore, even if the claim is interpreted as meaning an adapter and lead unitarily formed, which is the invention disclosed in the application, the invention would still be obvious, under In re Larson, 144 USPQ 347 (CCPA 1965). Appellant distinguishes Larson on the grounds that in Larson, a single prior art reference taught the parts secured together as a single unit. However, the Fain adapter only operates as intended when the adapter 40 is combined with a lead, such as the lead taught in Stutz. The Fain adapter is useless without lead(s) attached to the adapter. Fain does not describe the details of the lead, because knowledge of such leads, such as the Stutz lead, was well known in the art. Therefore, Larson is not distinguished because in both cases, the separate parts were intended to be secured together.

Appellant argues that there is no suggestion to combine the Stutz and Fain references. However, the Fain device only operates when it is combined with a lead, such as the lead taught

Art Unit: 2833

in Stutz. Without such a lead, the Fain device is useless. Therefore, clearly it would have been obvious to combine a lead and an adapter, so that the adapter would operate in its intended manner.

Regarding claims 4, 5, 11, and 12, the examiner concedes that the prior art does not suggest the lead as claimed, including the aperture extending through the adapter as claimed. This was communicated to Appellant's attorney in a telephone interview on 8/31/00. On 9/1/00, Appellant's attorney indicated that the subject matter of dependent claims 4 and 11 would not be incorporated into the independent claims to put the case in condition for allowance.

Appellant argues that the claimed invention serves a different purpose than Fain. The relevance of this argument is not apparent to the examiner in view of what is claimed. Furthermore, the examiner disagrees because the Fain device performs the same function as Appellant's device, namely Fain provides for "multiple leads plugged into a single port" and "allows a plurality of leads coupled to a single port of the header to simultaneously stimulate." (Appellant's Brief, page 9, lines 20-24).

Regarding claim 2, Appellant appears to be arguing that Fain does not teach a lead. In response to Appellant's arguments against the Fain reference individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). Stutz is cited for teaching the

Art Unit: 2833

lead as claimed. Appellant argues that the Office action does not provide a reference describing a lead. However, Stutz is referred to only for teaching a lead, such as the lead claimed by Appellant.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

Conferees:

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September 8, 2000

P. Bradley
[Faint stamp: RECEIVED SEP 11 2000]

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